

International Conference on Harmonization (ICH)
M2 EWG Meeting - Summary
Brussels, 04 February – 07 February 2002

Participants:

EU: Stan van Belkum, Miguel Bley, M. T. Carrasco Benitez, Tim Buxton

EFPIA: Gabriele Disselhoff, Andrew Marr, Said Ikazban, Raj Long

FDA: Greg Brolund (Rapporteur), Melissa Chapman, Bill Ridgely, Norman Schmuff

PhRMA: Kris Arora, Bob Hizer

MHLW: Tetsunari Kihira, Mihoko Okada

JPMA: Yuichi Nagoshi, Tetsuro Shimokariya, Hitoshi Asano, Harv Martens, Keiji Sawamukai, Koichi Takahashi

Observer: Bob Kapitany (Canada), John Hems (IGPA), Andreas Franken (WSMI)

Following actions have been taken / agreements were reached:

- The open questions from the last meeting on the specification document were discussed and agreed.
- IWGs CTD Q, CTD S, CTD E were consulted on their requirements for logical documents. Outstanding questions were clarified and resolved.
- The specification document with all its appendices was checked in detail and all comments received by different parties were taken into consideration.
- The Step 2 eCTD specification document v2.0 (with DTD v1.0 dated February 06, 2002) was signed by the six parties.
- DTD 1.0 dated February 06, 2002, will be frozen (for anything other than bug fixes) until the September 2002 meeting. Bug fixes to the DTD will be reflected in appendix 4 of the specification.
- Discussed the actions to be taken before the next meeting (see table below).

Documents distributed:

- 1 page summary
- Specification document v2. 0 (with DTD v1.0 dated February 06,2001)

The next meeting is in Washington, September 09 - 12, 2002.